K131302

# 510(k) Summary

**This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.**

**Applicant**

Name: Dongguan Prestige Sporting Goods Co., Ltd.
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NOV 26 2013

**Date prepared:** Oct. 10, 2013

**Device**

Trade name: SOLAX
Model: ZIPPY scooter
Common name: Electrical scooter
Classification name: Motorized three-wheeled vehicle
Medical specialty (Panel): Physical Medicine Device
Regulation number: 890.3800
Product Code: INI
Classification: Class II

**Predicate device**

Trade name: SOLAX
Model: MOBIE scooter
Manufacture: Dongguan Prestige Sporting Goods Co., Ltd.
510(k) number: K122749
Regulation number: 890.3800
Product Code: INI
Classification: Class II

**Intend use of device**

It is a motor driven, indoor and outdoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated position.

**Device description:**

The ZIPPY scooter consists of a retractable platform which connects the two front wheels and two rear wheels, an adjustable tiller, a lead acid battery with an off-board charger, a motor/electromagnetic brake assembly, a electric motor controller and a seat /backrest set. It can be retracted for transport in a car trunk.

The patient uses the tiller handle/handlebar for steering and a thumb operated potentiometer throttle control lever located at the top of the tiller to engage and disengage the scooter motion in both the forward and reverse directions. When the throttle control lever is released, the electromagnetic brake will be actuated and the scooter is slow to stop.

**Summary of non-clinical testing**

The ZIPPY scooter complied with the requirements of ANSI/RESNA WC. Vol. 1 Sec. 7, Sec 8 and sec. 21, CISPR 11, IEC 60335-2-29, IEC 60601-1, IEC 61000-4-2, IEC 61000-4-3, IEC 61000-4-8, ISO 7176-1, ISO 7176-2, ISO 7176-3, ISO 7176-4, ISO 7176-5, ISO 7176-6, ISO 7176-9, ISO 7176-10, ISO 7176-11, ISO 7176-13, ISO 7176-14, ISO 7176-15, ISO 7176-16,, ISO 14971, ISO 10993-1, ISO 10993-5, and ISO 10993-10.

**Statement of substantial equivalence**

The design and technological characteristics of the ZIPPY scooter is basically similar to the predicate device chosen. They have same intended use of a motor driven, indoor and outdoor transportation vehicle to provide mobility to a disabled or elderly person limited to a seated position.

There are minor differences between the devices including overall dimensions, distances between front wheels and pre-charging distance do not alter the intended use function and use of the device. Moreover, the non-clinical tests and the predicate comparisons demonstrate that these differences in their technological characteristics do not raise any questions as to the safety and effectiveness. Therefore the ZIPPY scooter is substantially equivalent to the MOBIE (K122749).

**Conclusion**

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, Dongguan Prestige Sporting Goods Co., Ltd. concludes that, ZIPPY scooter is substantially equivalent to predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 26, 2013

Dongguan Prestige Sporting Goods Co., Ltd.
c/o Ms. Junnata Chang
16F-2(16A), No. 462, Sec. 2
ChongDe Rd., Beitun Dist.
Taichung 406
TAIWAN

Re: K131302
Trade/Device Name: SOLAX ZIPPY SCOOTER
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized three-wheeled vehicle
Regulatory Class: Class II
Product Code: INI
Dated: October 10, 2013
Received: October 22, 2013

Dear Ms. Chang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K131302

Device Name: SOLAX ZIPPY SCOOTER

Indications For Use:

The device is a motor driven, indoor and outdoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated position.

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use __X___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of Center for Devices and Radiological Health (CDRH)

Joyce M. Whang -S